UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 18 2018

OPP Decision Numbers: 534367
EPA File Symbols: 93348-R
Product Names: HALAMID
EPA Receipt Date: September 15, 2017
EPA Company Number: 93348
Company Name: AXCENTIVE SARL

Dr. Matthew Brooks
Regulatory Agent
Axcentive SARL c/o Ag-Chem Consulting
12644 Chapel Road
Clifton, VA 21024

Dear Dr. Brooks:

The agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA), as amended by the Pesticide Registration Improvement Extension Act. The agency has determined that your application did not pass the preliminary technical screen and therefore must be rejected. The agency's decision to make this determination is based on the following chronology, including correspondence with you and efforts undertaken to resolve the issues.

- February 5, 2018- The agency emailed you a 10-Day Deficiency Letter dated February 5, 2018 that outlined deficiencies with the application. Specifically, the following issues were identified:
    - Efficacy Screening failures included:
        - Certificate of Analysis were needed to confirm that the product batches were tested at the lower certified limit.
        - Directions for use on the label for disinfection are unclear. Instructions for preparing the use solution for disinfection should be clear. Label should specify disinfection is only for hard, non-porous surfaces.
        - Fogging claims should be removed or supported by data. (Please see the fogging document included with this letter)
            - Currently the agency does not have an existing protocol for this claim; however; registrants have been asked to submit efficacy testing data for this claim to be evaluated or for those without data, to submit a draft efficacy test protocol for approval by the agency.
        - Claims against viruses, fungi, and yeast, are not supported by the submitted data. Product performance testing (810.2200 – Disinfectants for Use on Environmental Surfaces) must be submitted.
        - Claims for emergency disease or contagious disease control should be removed.

        - The claims are not in compliance with 40 CFR 156.10(a)(5) and are considered false and misleading. The proposed language implies:
            - That the product has enhanced efficacy beyond what is demonstrated by the data. Testing demonstrates organism removal on a surface, not disease reduction in a person. There is no data to demonstrate a direct causal link in this regard.
            - The statement may be true but could give a false or misleading impression to the end user; resulting in reduced precautions
- Acute Toxicity Screening failures included:
    - Acute Oral Toxicity: Guideline 870.1100- The submitted acute oral toxicity study report from 2/8/1967 does not contain the Good Laboratory Practice (GLP) certification statements required in 40 CFR §160 (though the study was conducted before such certifications were required). (Note: This is in reference to the 1967 study report, not the 2018 document that includes a copy of that report.) The study report has other deficiencies also, as the report is incomplete by current standards. For example, it does not report mortality data for each sex separately.
    - Acute Dermal Toxicity: Guideline 870.1200/ Acute Oral Toxicity: Guideline 870.1100- For the acute oral toxicity study citations from the literature, and for the one acute dermal toxicity study citation from the literature, we need to see the full study report, not just a citation or summary. We also need a statement from the applicant as to why they believe the test material in the studies is similar to HALAMID.
    - Acute Inhalation Toxicity: Guideline 870.1300- The cited (with copy submitted) acute inhalation toxicity study report is unacceptable
        - The submitted acute inhalation toxicity study report does not contain the Good Laboratory (GLP) certification statements required in CFR §160.
        - The purity of the Chloramine T tested was not stated.
        - Required particle size distribution data were not presented but were only summarized.
        - Data used for determining the gravimetric concentration were not presented.
    - The submitted eye irritation and skin irritation study reports do not identify the chemical, though they do state the purity. We need a statement explicitly clarifying that the substance tested was Chloramine T in study MRID 50403518 (eye irritation) and MRID 50403516 (skin irritation).
- Risk Assessment and Science Support Screening failures included:
    - Mammalian Toxicology data submitted in support of the proposed uses of the product did not sufficiently address and/or did not include data to support one or more of the following guidelines (Please see the Technical Screening Review, pages 2-3 for additional details):
        - 870.3465- 24/90-day Inhalation study
        - 870.6200- Neurotoxicity screening battery
        - 870.7800- Immunotoxicity study

        - 870.2600- Dermal sensitization waiver request
        - 870.1300- Acute inhalation waiver request
        - 870.7485- Metabolism and pharmacokinetics
    - Occupation and Residential Exposure data was deficient as no occupational exposure data was cited in support of the proposed uses of the product. (Please see the original Technical Screening Review, pages 3-4):
        - 875.1200/ 875.1400- Open pour powder for fogging (dermal/ inhalation) for Poultry Premises
        - 875. 2500- Postapplication inhalation for Poultry Premises
        - 875.1200/875.1400- Trigger pump sprayers & open pour powders for Veterinary Premises
    - Ecological Effects data was deficient as studies submitted contained only summary data for following four guidelines:
        - 850.2100- Avian acute oral toxicity
        - 850.1010- Freshwater aquatic invertebrate toxicity
        - 850.1075- Freshwater fish acute toxicity
        - 850/4500- Green algal toxicity
    - Also, you did not address other ecotoxicity studies for the down-the-drain environmental risk assessment of five additional guidelines:
        - 850.1035- Mysid acute toxicity
        - 850.1025- Oyster acute toxicity
        - 850.1075- Estuarine/marine fish acute toxicity
        - 850.1300- Aquatic invertebrate life cycle
        - 850.1400- Fish early life-stage toxicity
    - Environmental Fate data was deficient because the requirements lacked an associated study or waiver (Please see the Technical Screening Review, pages 5-7):
        - 835.4300- Aerobic Aquatic Metabolism Study
- February 5, 2018- You contacted the agency in order to request a conference call to discuss the deficiencies outlined in the 10-day Deficiency Letter. The conference call was held on February 6, 2018 at 3:30pm in which we clarified questions regarding the 10-day response time frame.
- February 15, 2018- You notified the agency that you had sent your response to the 10-day Deficiency Letter via FedEx on February 14, 2018 and submitted a copy of the response letter with the studies and other data attached. The agency acknowledged receipt of the email and requested an electronic copy of the information that you submitted via FedEx.
- February 16, 2018- You notified the agency that you would not be able to send the studies until you returned to your office the week of February 19, 2018.
- February 26, 2018- The agency contacted you, to alert you that the studies which you stated were submitted via FedEx had not yet been received and processed. You responded via email with an amended report for the oral toxicity, an amended report for efficacy and a response letter with revised label.
- February 27, 2018- The agency found this information to be insufficient and emailed you in order to confirm that all materials intended for submission in the response were complete. You

confirmed this via email. Based on the review of your submitted response, the agency found this information still to be deficient as the items identified in the technical screening reviews were not successfully addressed. Specifically, the Risk Assessment and Science Support and Acute Toxicology technical screening items were not addressed at all. In addition, for the Efficacy technical screening, the Certificate of Analysis only provides concentration for 2 of 3 batches; for batch 1607681176, it looks like the concentration for a different batch 1607681174 was provided instead. Also, for base claims, data should be conducted at the lower certified limit (LCL) of the active ingredients. These batches were formulated at nominal and diluted according to nominal rates, rather than LCL.

The agency has determined that your application did not pass the preliminary technical screen and therefore must be rejected. Any future submissions to the agency will be considered a new application and subject to the full registration service fee, as well as another initial content screen and preliminary technical screen.

In certain cases, applicants may be eligible for a partial refund of no more than 75% of the PRIA fee as a result of their application's rejection for failure of its preliminary screening. In this case of your application, you received a 75% waiver of the registration service fee and only paid 25%. As a result, no refund is due.

If you have any questions, please contact Demson Fuller at Fuller.Demson@epa.gov or (703) 308-8062.

Sincerely,

Richard P Keigwin, Jr.

Richard Keigwin, Jr., Director
Office of Pesticide Programs, (7510P)
US Environmental Protection Agency